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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,354	10/06/2005	Keith M. Rosiello	350959-0004 THMX-001US	2403
48329 7590 04/15/2008 FOLEY & LARDNER LLP 111 HUNTINGTON AVENUE 26TH FLOOR BOSTON, MA 02199-7610			EXAMINER VERMEULEN, MICHELLE ANNE	
			ART UNIT 3767	PAPER NUMBER
			MAIL DATE 04/15/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/552,354	Applicant(s) ROSIELLO ET AL.	
	Examiner Michelle A. Vermeulen	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/06/2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 and 31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 and 31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10/06/2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>02/01/2006 and 11/29/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings are objected to because Figs. 2a and 2b are referred to in the written description, but not included in the drawings.
2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 231, 233, 235, 238, 242, and 245.
3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 1004, 1902, 1903, and 2302.
4. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New

Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

5. Claims 10, 13, 14, 15, and 31 are objected to because of the following informalities:

- a. Claim 10 recites the limitation “the thermal medium” in line 1 and is dependent on claim 1. There is no antecedent basis for this limitation in claim 1. For examination purposes, claim 10 is assumed to depend on claim 9.
- b. Claims 13 and 14 recite the limitation “the controller” in lines 2 and 1, respectively, and both claims are dependent on claim 1. There is no antecedent basis for this limitation in claim 1. For examination purposes, claims 13 and 4 are assumed to depend on claim 2.
- c. Claim 15 recites the limitation “the power source” in line 1 and is dependent on claim 2. There is no antecedent basis for this limitation in claim 1. For examination purposes, claim 15 is assumed to depend on claim 14.
- d. Claim 31 recited the limitation “the first tube” in line 7 and “the first tube and the second tube” in line 11. There is no antecedent basis for these limitations in the claim. For examination purposes, “the first tube” is assumed to be the “insulative tube” from line 6 and “the second tube” is assumed to be the “fluid delivery tube” from line 7.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-26 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 1 recites the limitation "the fluid delivery tube" in line 5. There is insufficient antecedent basis for this limitation in the claim. It is unclear whether "the fluid delivery tube" is intended to refer to "a fluid delivery line" in line 2 or "a tube" in line 3. Additionally, "the fluid delivery tube" is recited in claim 11, line 1; claim 12, line 1; claim 22, line 2; claim 23, line 2; claim 24, line 2; and claim 25, line 2.

9. Claim 3 recites the limitation "the second tube" in line 2. There is insufficient antecedent basis for this limitation in the claim. Additionally, "the second tube" is recited in claim 18, line 2 and claim 21, line 2.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 1-8, 11-14, 16-19, 22-25, and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by Lenker (U.S. 6,746,439).

12. Lenker discloses an apparatus for fluid administration with distributed heating (Figs. 1-8) comprising warming fluid administration tubing (112, 146, 250), a temperature probe (128), and a resistive heating element (196), or alternatively, a heater (150), equivalent to the tube, thermal sensor, and heating element, respectively, of claim 1. Concerning claim 2, there is a controller (Fig. 1, 122). Regarding claim 3, the resistive heating element (196) is adjacent and spaced from lumen (252) (Fig. 8). Additionally, it could be embedded in outer wall (Fig. 2, 138) spaced apart from inner tube (134) (Col. 8, lines 37-40). Concerning claim 4, heat exchange fluid (158) flows through lumens (166) which are positioned between inner wall (168) and outer wall (170) of fluid delivery tube (146). With respect to claims 5-8, the heating elements (196) may be circular, I-beam, flat, partial cylinders, or other shapes (Col. 8, lines 50-52) and run the length of the tubing (Col. 8, lines 9-11). Concerning claim 11, there is a drip chamber (142) used to fluidly connect I.V. bag (108) to tubing (112) (Fig. 1). Regarding claim 12, there is an I.V. cannula or needle (118). With respect to claims 13 and 17, resistive heating elements (196) are electrically connected to controller (122) through heater power/control line (124) (Col. 8, lines 34-36). Concerning claim 14, the controller (122) transmits power (Col. 3, lines 56-59). Regarding claim 16, at least a portion of the fluid administration system will be sterilized prior to use (Col. 8, lines 54-55). With

respect to claim 18, the controller (122) sends commands to the heater (150) according to the information received from the temperature feedback line (130) (Col. 7, lines 59-62). Concerning claim 19, the temperature feedback line (130) connects the temperature probe (128) to the controller (122) and heater (150) is connected to the controller (122) through heat exchange power/control line (154). Regarding claim 22, a delivery pump (116) pumps fluid at a set flow rate (Col. 3, lines 42-44) as determined by the controller (122) (Col. 3, lines 57-59). Concerning claim 23, tubing wall (256) transfer heat from heating elements (196) to delivery fluid (110) contained inside lumen (252). With respect to claim 24, an insulation layer (Fig. 7, 194) is optional. Regarding claim 25, heat exchange fluid (158) flows through lumens (166) which are positioned between inner wall (168) of fluid delivery tube (146) and insulative tube (194). Concerning claim 31, Lenker discloses a controller (122), a fluid delivery tube (146), an insulative tube (194) surrounding the fluid delivery tube (146), a temperature probe (128), a heating element (196), and heat exchange fluid (158) that travels through lumens (166) positioned between inner wall (168) and outer wall (170) of fluid delivery tube (146).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 9, 10, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker (U.S. Patent No. 6,746,439).

15. Lenker discloses the invention substantially as claimed as described above. However, he fails to describe the resistive heating element (196) and the heat exchange fluid (158) flowing through lumens (166) (equivalent to thermal medium) in the same embodiment.

16. It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the resistive heating element embodiment (Fig. 8) with the heat exchange fluid embodiment (Figs. 4-7) to obtain a fluid warming system wherein a fluid thermal medium is surrounding a heating element in order to heat the I.V. fluid uniformly.

17. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker (U.S. Patent No. 6,746,439) in view of Swenson (U.S. Patent No. 5,195,976).

18. Lenker discloses the invention substantially as claimed as described above. However, he fails to teach a one-time or rechargeable battery pack or AC or DC power as the power source.

19. Swenson teaches an apparatus in the same field of endeavor for the purpose of intravenous fluid temperature regulation. The apparatus comprises an energy source consisting of a direct current power supply, AC current, or battery power (Col. 5, lines 28-32).

20. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the apparatus of Lenker to include the power source of Swenson in order to run the controller (Col. 4, lines 13-18).

21. Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker (U.S. Patent No. 6,746,439) in view of Cassidy et al (U.S. Patent No. 6,175,688 B1).

22. Lenker discloses the invention substantially as claimed as described above. However, he fails to teach a temperature operated valve.

23. Cassidy teaches an intravenous fluid heater in the same field of endeavor for the purpose of delivering warmed fluids to a patient. The intravenous fluid heater comprises a valve system (702) that opens and closes fluid flow through tubing depending on the temperature (Col. 12, line 64-Col. 13, line 36).

24. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the apparatus of Lenker to include a temperature operated valve in order to prevent the administration of fluid to a patient at an undesired temperature as taught by Cassidy.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michelle A. Vermeulen whose telephone number is (571) 270-3812. The examiner can normally be reached on Mon-Thurs, 8:30 am-6 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michelle A Vermeulen/
Examiner, Art Unit 3767

| April 8, 2008

/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767